



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

MAY 10 1999

7771 '99 MAY 10 1999  
Re: Rebexine Mesylate  
Docket No. 99E1070

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
U.S. Patent and Trademark Office  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,229,449 filed by Pharmacia & Upjohn S.p.A. under 35 U.S.C. § 156.

A review of the Food and Drug Administration's official records indicates that this product is undergoing a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that if approved it is expected to represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

Should you conclude that the subject patent is eligible for an interim patent term extension, please advise us accordingly.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Raymond G. Arner  
Pharmacia & Upjohn  
Intellectual Property Services  
301 Henrietta Street  
Kalamazoo, MI 49001

99E-1070

LET 2

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

7770 '99 MAY 11 A9:48

**Memorandum**

Date: **MAY 10 1999**

From: **Brian J. Malkin, Associate Director for Patents and Hearings  
Health Assessment Policy Staff (HFY-20)**

Subject: **Patent Term Restoration Application  
for **Reboxitine Mesylate****

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **99E1070** stating that this particular patent is eligible for regulatory review.. The Patent Number is **4,229,449**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.